

§ 876.5250

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(2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]

§ 876.5250 Urine collector and accessories.

(a) *Identification.* A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are:

(1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and

(2) A urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

(b) *Classification*—(1) *Class II (special controls) for a urine collector and accessories intended to be connected to an indwelling catheter.* The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

(2) *Class I (general controls).* For a urine collector and accessories not intended to be connected to an indwelling catheter, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998; 65 FR 2317, Jan. 14, 2000; 66 FR 38802, July 25, 2001; 73 FR 34860, June 19, 2008]

§ 876.5270 Implanted electrical urinary continence device.

(a) *Identification.* An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted electrical urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted electrical urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted electrical urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]